

## **REMARKS**

### **Claim Amendments**

Claims 5-7, 16-18 and 24 have been amended to include the current status of each claim using the proper identifiers. Additionally, Claims 51-61 have been added herein. Support for new Claims 51-61 can be found throughout the specification and in Claims 29-31, 36-37, 42-44 and 48-50 as originally filed. No new matter has been added.

### **Claim Objections**

Claims 5-7, 16-18 and 24 have been amended to include the current status of each claim using the proper identifiers. Reconsideration and withdrawal of the rejection are requested.

### **Restriction/Election**

Applicants continue to traverse the Restriction Requirement (in-part) and the Election of species requirement. A Petition to the Director to review the Restriction Requirement (hereinafter "Petition") is being submitted concurrently herewith.

In the previous response to the Restriction Requirement, Applicants inadvertently canceled, rather than withdrawn, the claims of Groups VI and VIII which Applicants requested be combined with Groups III and IV in the instant application. New Claims 51-61 have been added to support the Petition and the traversal of the Restriction Requirement.

### **Rejection of Claims 23-23 Under 35 U.S.C. §112, First Paragraph**

Claims 23-23 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office Action states that the terms "antibiotic agent" and "beta-lactam antibiotic" were not described in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants disagree. First, the terms "antibiotic agent" and "beta-lactam antibiotic" are sufficiently described in the instant specification at paragraph [0076] of the application as published. Second, the terms are well known and understood to one skilled in the art, and as such, need not be described in haec verba in the specification to satisfy the written description requirement (*Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 923). Finally, sufficient

support in the description was found for these terms which were claimed and patented in a related application to the instant application (See US Patent No. 6,599,889).

The Examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96. The instant Office Action fails to meet this standard. The Office Action merely states that the terms were not sufficiently described without an explanation, especially in view of the reasons stated above by the Applicants, as to why the description is inadequate. Reconsideration and withdrawal of the rejection are requested.

#### Rejection of Claims 23-23 Under 35 U.S.C. §112, First Paragraph

Claims 23-23 are rejected under 35 U.S.C. §112, first paragraph, because, according to the Office Action, while being enabling for methods of use of the instant compositions of compounds of Formula (II) further comprising the antibiotic agent penicillin, does not reasonably provide enablement for the instant compositions comprising an antibiotic agent other than penicillin.

Applicants disagree. As stated above, the term antibiotic is known and understood by one skilled in the art. Additionally, as recognized on page 6 of the Office Action the level of ordinary skill in the art is high. Applicants respectfully submit that one skilled in the art would be taught by the specification how to practice the claimed invention without undue experimentation. One skilled in the art could easily reproduce the results by simply following the disclosed teachings and examples. As to other antibiotics, undoubtedly some screening using the instant teachings would be required. However, these experiments, which would require no modification of the instant teachings, would not be undue. The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *Massachusetts Institute of Technology v. A.B. Fortia*, 227 U.S.P.Q. 428 (Fed. Cir. 1985). In this field, scientists typically engage in such screening, and would have to do so no matter how many antibiotics are exemplified. In addition, the enablement requirement is met if the description enables any mode of making and using the invention. *Johns Hopkins University v. Cell Pro Inc.*,

47 U.S.P.Q.2d 1705, 1718 (Fed. Cir. 1998), *citing Engel Indus., Inc. v. Lockformer Co.*, 20 U.S.P.Q.2d 1300, 1304 (Fed. Cir. 1991). Applicant has clearly met this requirement.

Reconsideration and withdrawal of the rejection are requested.

Rejection of Claims 6-7 and 17 Under 35 U.S.C. §112, Second Paragraph

Claims 6-7 and 17 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

Applicants disagree. It is well understood to one skilled in the art that the term “carbocyclic” falls within the meaning of cycloalkyl or aryl moiety. Reconsideration and withdrawal of the rejection are requested.

Double Patenting

Claims 16-18 and 22-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claim 6 of Besterman et al. (US 6,608,046).

Enclosed herewith is a terminal disclaimer whereby MethylGene, Inc., owner of 100% interest in the instant application, disclaims any portion of the term of any patent granted on this application that would extend beyond the natural expiration of U.S. Patent No. 6,608,046, or beyond the term of common ownership of any patent granted on this application and U.S. Patent No. 6,608,046.

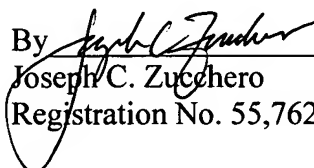
**CONCLUSION**

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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